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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,434	07/18/2002	Michael B Thornton	PI-0137 USN	3714

22428 7590 09/30/2004

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/069,434	THORNTON ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-17,19,22 and 27-29* is/are pending in the application.

4a) Of the above claim(s) *1,2,10,13,15-17,19,22 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-9 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to restriction requirement filed August 2, 2004, is acknowledged. Claims 1-50 were originally present in this application.

2. ***Election***

Applicant's election with traverse of Group 2, claims 3-9 & 11, drawn to a polynucleotide of SEQ ID NO: 4 encoding polypeptide of SEQ ID NO: 1, vector, host cell and method of making the polypeptide, is acknowledged.

Applicants in their election response argue that claims 12, 14, 18, 20-21, 23-26 and 30-50 were previously cancelled without prejudice or disclaimer as per Item 13 of PTO-1390, dated February 20, 2002. However, this paper could not be identified or traced from among the papers recorded in the Image File Wrapper (IFW) for this applications.

Applicants' are requested to resubmit this paper in order to complete and clarify the prosecution history. For the purpose of this office action claims 12 and 48 are not included among the claims under consideration. Also for the purpose of this Office Action ONLY, claims 12, 14, 18, 20-21, 23-26 and 30-50 are treated as cancelled, subject to resubmission of Applicants' Item 13 of PTO-1390, dated February 20, 2002.

The traversal is on the ground(s) related to Commissioner's directive in dealing with number of nucleic acid sequences.

>803.04 Restriction - Nucleotide Sequences [R - 3]

Applicants citing statutes to rules of practice in patent cases cite the Commissioner directive in dealing with number of nucleic acid sequences. MPEP 803.04 is reproduced below.

By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121.

Pursuant to this statute, the Rules of Practice in Patent Cases provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant . . . to elect that invention to which his claim shall be restricted." 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application.

Up to 10 nucleic acid sequences may well be one sequence. Further, in the single elected sequence of SEQ ID NO: 4 we are also searching for fragments of nucleic acid encoding SEQ ID NO: 1, of unspecified length, which may be 5-1000 contiguous nucleotides or amino acids residues [see instant specification, page 14, lines 15-26, for example]. It may be noted that the purpose of waiving the requirements of 37 CFR 1.141 et seq. was to aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office. However, searching for 10 nucleotide sequences, which are about several hundred nucleotides in length (such as SEQ ID NO: 4) and fragments thereof, and from a variety of sequence data bases will place a serious burden upon the Examiner, and the benefits of the ***dual*** purpose of the Commissioner's directive i.e. (1) aiding the biotechnology industry

without (2) an undue burden on the Office, will be lost.

Applicant's election with traverse of Group 2, claims 3-9 & 11 is acknowledged. The traversal is on the ground(s) that "when the U.S. Patent and Trademark Office considers international applications ... during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 wi11 be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. ...

In applying PCT Rule 13.2 ... to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching ...claims to the categories which meet the requirements of PCT Rule 13.2.

> Beginning at page 4, applicant cites Example 17, Part 2 of Annex B to the Administrative Instructions Under the PCT, which states:
>
> *Example 17*
>
> Claim 1: Protein X.
>
> Claim 2: DNA sequence encoding protein X.
>
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

Applicant argues that in the present case, unity of invention does exist at least as between claims 1-2 and 16-17 of Group 1, which encompass the polypeptides of SEQ ID NO:1, and claims 3-9 and 11 of Group 2, which encompass in part the polynucleotides which encode those polypeptides. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-9, 11 and 16-17 of Groups 1 and 2, and examine those claims in a single application.

In particular, as Applicants argue below, it is respectfully requested that claims 1-2 and 16-17 of Groups 1, 3 and 5, which encompass the polypeptides depicted in SEQ ID NO:1-3, be rejoined with claims 3-9 and 11 of Groups 2, 4 and 6, which encompass the polynucleotides which encode those polypeptides.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Furthermore, according to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions of Groups I and II do not have unity of invention because the technical feature of Group I is not a contribution over the prior art.

The argument is considered and found not persuasive because claim 1 is drawn to not only any polypeptide having 90% identity to SEQ ID NO: 1 or a biological active fragment thereof, but also any immunogenic fragment with no activity or homology limitation, which therefore, reads upon any polypeptide, for example, Lowe et al. Gene, 93: 277-283 (1990) [a copy of this prior art was submitted by the Applicants], a carbonic anhydrase [or a lyase], which is 62.4% similar to Applicants' polypeptide of SEQ ID NO: 1 [see the enclosed sequence search alignment] and has several 5 or more identical contiguous amino acid residues. The reference reads upon Applicants' biological active fragment (see claim 1) which is as per Applicants' definition can vary from 5-1000 contiguous amino acids, [and per the claim, no limitation with respect to the size or function is pertinent] and since the phrase 'biological active' is so vaguely defined as to mean any fragment(s) that can be with or without any enzymatic or immunogenic activity, and such a fragment is disclosed in the carbonic anhydrase sequence of Accession No. CRHU1. As a consequence the cited prior art defines that the technical feature so claimed as not a contribution over the cited prior art.

Therefore, Unity of Invention is lacking.

The lack of unity determination is still deemed proper and is therefore made FINAL.

3. **Claims withdrawn** :

Claims 1-2, 10, 13, 15-17, 19, 22 & 27-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed as per response filed August 2, 2004.

4. Claims 12, 14, 18, 20-21, 23-26 and 30-50 were previously cancelled without prejudice or disclaimer as per Item 13 of PTO-1390, dated February 20, 2002 [This paper has to be resubmitted by the Applicants, as explained above].

5. Claims 3-9 & 11 [SEQ ID NO: 4 encoding polypeptide of SEQ ID NO: 1] are pending and under consideration in this examination.

6. ***Specification/continuation data***

(a) The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

(b) This application filed under 35 USC 119(e) lacks the necessary reference to the prior application(s). This application claims the benefit of US Provisional Application No. 06/ , filed ..., should be entered following the title of the invention or as the first sentence of the specification. Also, the present status of all parent applications should be included.

7. ***Claim Objections***

Claims 3-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. Claims 3-9, directly or indirectly depend upon non-elected claim 1. Amending the claims to place the claims in proper dependent form and referring to the elected sequence ID only will overcome this objection.

8. **Written Description**

Claims 3-9 & 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of polynucleotide molecules [90% similarity to SEQ ID NO: 4] or wherein polynucleotide(s) (or DNA) encode polypeptide sequence(s) which are is 90% identical to the amino acid sequence of SEQ ID NO : 1, with no defined function associated with it.

The specification describes SEQ ID NO: 1 as human lyase referred to as 'HLYA', encoded by the DNA sequence of SEQ ID NO : 4. The specification does not contain any disclosure or description of the structure and function of all DNA/polypeptide sequences that are 90% identical to SEQ ID NO : 4 or 1, or wherein such a DNA would likely encode polypeptide(s) having lyase activity. Lyases are a class of enzyme that catalyze the cleavage of C-C, C-0, C-N, C-S, C-(halide), P-O, or other bonds without hydrolysis or oxidation to form two molecules, at least one of which contains a double bond (see instant specification, page 1, lines 10-12). These lyases based upon the functional cleavage will utilize distinct substrate(s) and may be decarboxylases, carbonic anhydrase, l-phenyl ammonia lyase(s), S-hydroxynitrile lyase(s), pectate lyase(s), hydroperoxide lyase(s), etc. However, the specification fails to describe SEQ ID NO: 1 to have any specific lyase activity. Further, the specification as filed does not describe size of the immunogenic or size or function of any biologically active fragment. The genus of polynucleotides

or polypeptides that comprise these DNA molecules is a large variable genus with the potentiality of encoding many different proteins with no function, or polypeptides with no associated regulatory or biochemical function. Therefore, many functionally unrelated DNA or polypeptide molecules are encompassed within the scope of these claims, including partial DNA sequences or polypeptide fragments. The specification discloses only 3 species each of the polypeptide [SEQ ID No. 1-3] and 3 species of the encoding polynucleotide [SEQ ID No. 4-6) of the claimed genus, which has not been disclosed to be representative of each other, and is therefore insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus of polypeptides/polynucleotides having 90% similarity and there fragments and using these sequences in the preparation of vector, host cell and for making the polypeptide recombinantly. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

9. ***Enablement Rejection***

Claims 3 & 6-9 & 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid (or polynucleotide) sequence of SEQ ID NO : 4 encoding a specific lyase (?) of SEQ ID NO : 1, does not reasonably provide enablement for : any fragment, [biologically active or immunogenic] of SEQ ID NO : 1 or 4; or that encoding a protein having 90% homology to SEQ ID NO : 1 or a nucleic acid having 90% similarity to SEQ ID NO: 4.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. &

Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The specification provides guidance and examples for making an isolated polynucleotide comprising SEQ ID NO: 4 and the encoded lyase (non-specific) having a sequence of SEQ ID NO : 1. However, the specification does not teach specific fragment molecules of these sequences or does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. The state of the art as exemplified by Attwood et al. [Comput. Chem. 2001, col. 54(4), pp. 329-39] is such that "..we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given the knowledge only of its sequence or structure in isolation" (see abstract and the entire publication). Further Ponting [Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29] states that "...predicting function by homology is a qualitative, rather than quantitative process and requires particular care to be taken, due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domain in proteins" (see abstract and the entire publication).

The standard of meeting enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotide is enormous and entails selecting specific nucleotides to change (deletion,

insertion, substitution or combination thereof) in a polynucleotide to make a claimed polynucleotide and determining by assays whether the polypeptide has activity. The specification does not provide guidance with respect to the specific structural/catalytic amino acids and the structural motifs essential for enzyme structure/function which must be preserved. Thus, searching for the specific nucleotides to change (deletion, insertion, substitution or combination thereof) in a polynucleotide to make polynucleotide that is at least 90% identical to a polynucleotide comprising nucleotides of SEQ ID NO: 4 [or polypeptide sequence of SEQ ID No.1], and transforming host cell or organism [including human] using the isolated nucleic acid(s) is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no guidance is provided with respect to the structural motifs essential for enzyme structure and activity/function which must be preserved. Further, the disclosed meaning of the phrase 'biologically active' [specification], page 12, lines 21-22] is a protein having structural, regulatory **or** biochemical functions. These lyases based upon the functional cleavage will utilize distinct substrate(s) and may be decarboxylases, carbonic anhydrase, l-phenyl ammonia lyase(s), S-hydroxynitrile lyase(s), pectate lyase(s), hydroperoxide lyase(s), etc. However, the specification fails to describe SEQ ID NO: 1 to have any specific lyase activity.

Determining the biological function(s) would be highly unpredictable as no specific lyase function or enzyme assay using a particular substrate and associated with SEQ ID NO: 1 is described in the instant specification. Likewise, immunologically active" or immunogenic" refers to the capability of the natural, recombinant, or synthetic HLYA, or of any oligopeptide thereof, to induce a specific immune response in appropriate animals or cells and to bind with

specific antibodies, and such a fragment(s) is neither taught or guidance provided to one skilled in the art to prepare one from the sequences provided.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and structural motifs essential for activity/function which must be preserved in order to alter or modify the sequences as claimed. Without such a guidance, the experimentation left to those skilled in the art is undue.

10. **35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 7-8 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.
In the absence of the hand of man, naturally occurring cell, proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims 7 to recite wording such as "An isolated cell transformed with the ...".

Claim 8 is included in the rejection for failing to correct the defect present in the base claim(s).

11. **Utility**

Claims 3-9 & 11 are rejected under 35 U.S.C. 101 because the

claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants disclose a nucleic acid sequences (SEQ ID NO: 4) encoding the amino acid sequence of SEQ ID NO: 1. Based on reasonable sequence homology as per Examiner's sequence search discussed earlier the protein appears to belong to a family of Lyases, which is a generic asserted utility. Lyases belong to a family of enzymes which utilizes varying substrates and are involved in distinct biological processes. It is nearly impossible from sequence homology to determine specific function. Sequence homology may give clues to predictable function. However, in the instant case there cannot be any specific match between the Applicants' generic claimed function and SEQ ID NO: 1. The protein of SEQ ID NO: 1 has a more likely probability to be any of the member of lyase family. Even accepting the plausible utility of being a lyase, one of ordinary skill in the art would not know which is a substrate for the enzyme. The specification does not disclose a specific function of the polypeptide of SEQ ID NO: 1 and any activity data, its relationship to any disease, or any specific real world use. The specification describes generic functions for the protein, nucleic acid, and antibodies. The utility of the nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 1 which neither the gene or the polypeptide associated with a specific use or a disease. It appears that the main utility of the polypeptide and

nucleic acid is to carry out further research to identify the biological function and possible diseases associated with said function. A more than one page list of diseases associated with the lyase of SEQ ID NO: 1 is given on pages 38-39 of the instant specification. However, it is impossible to determine which of these diseases are truly associated the polypeptide of SEQ ID NO: 1. Substantial utility defines a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

12. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 3-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 depends on claim 1, and claim 1, line 6 recites the limitation 'biologically active fragment'. The disclosed meaning of the phrase 'biologically active' [specification], page 12, lines 21-22] is a protein having structural, regulatory **or** biochemical function. The claims are indefinite because it is unclear what activity is associated with such a biological function. In the broadest interpretation 'biologically active fragment' may be any protein fragment without a limitation to the size and with no defined function. Such a fragment would read on any di-peptide or tri-peptide.

Claims 3-9 are included in the rejection because of its dependence (directly or indirectly) on claim 1, and for failing to correct the defect present in the base claim(s).

13. ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Lowe et al. Lowe et al. [Gene, 93: 277-283 (1990)] teach a carbonic anhydrase [or a lyase], which is 62.4% similar to Applicants' polypeptide of SEQ ID NO: 1 [see the enclosed sequence search alignment] and has several 5 or more identical amino acids. Therefore inherently teaches 15 or more identical nucleotides encoding these 5 or more identical amino acids fragments, in the DNA sequence of Accession No. M33987. The reference reads upon Applicants' biological active fragment (see claim 1) which has no limitation with respect to the size or function of the fragment, and since the phrase 'biological active' is so vaguely defined (see item 12. above) as to mean any fragment(s) that can be with or without any enzymatic or immunogenic activity, and such a fragment is disclosed in the carbonic anhydrase sequence of Accession No. CRHU1 or that encoded by the corresponding DNA (Accession No. M33987) sequence (see Figures 1 & 2). The reference also teaches method of making the carbonic anhydrase by expression in host cell and recovering the protein. The claims are written so broadly as to be anticipated by the reference.

14. As per our records no PTO-1449 was filed.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 21, 2004